IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

ASTRAZENECA LP, ASTRAZENECA AB, ASTRAZENECA UK LIMITED, and ASTRAZENECA PHARMACEUTICALS LP, Plaintiff, v. MYLAN INC. and MYLAN PHARMACEUTICALS INC., Defendant.	Civil Action No. 1:15-CV-202

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca LP, AstraZeneca AB, AstraZeneca UK Limited, and AstraZeneca Pharmaceuticals LP (collectively "AstraZeneca" or "Plaintiffs"), by its attorneys, hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against defendants Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively "Mylan" or "Defendant"). This action relates to Abbreviated New Drug Application ("ANDA") No. 208597 ("ticagrelor ANDA") filed by Defendant with the U.S. Food and Drug Administration ("FDA") for approval to market generic versions of AstraZeneca's BRILINTA® (ticagrelor) drug product in tablet forms and in 60 mg and 90 mg dosage strengths, prior to expiration of AstraZeneca's U.S. Patent Nos. 6,251,910 ("the '910

patent"), 6,525,060 ("the '060 patent"), 7,250,419 ("the '419 patent"), 7,265,124 ("the '124 patent"), and 8,425,934 ("the '934 patent") that are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for BRILINTA® (collectively "the Orange Book Patents").

PARTIES

2. AstraZeneca is engaged in the business of creating, developing, and bringing to market revolutionary biopharmaceutical products to help patients prevail against serious diseases, including treatments for cardiovascular diseases.

3. Plaintiff AstraZeneca LP, the holder of New Drug Application ("NDA") No. 022433 for BRILINTA® (ticagrelor), is a limited partnership operating and existing under the laws of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803. Defendant specifically directed its Notice Letters to AstraZeneca LP.

4. Plaintiff AstraZeneca AB is a company operating and existing under the laws of Sweden, with its principal place of business at SE-151 85 Södertälje, Sweden. AstraZeneca AB is the owner of the '124 and '934 patents, and Defendant specifically directed its Notice Letters to AstraZeneca AB.

5. Plaintiff AstraZeneca UK Limited is a company operating and existing under the laws of the United Kingdom, with its principal place of business at 15 Stanhope Gate, London, United Kingdom W1Y 6LN. AstraZeneca UK Limited is the owner of the '910, '060, and '419 patents, and Defendant specifically directed its Notice Letters to AstraZeneca UK Limited.

6. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership operating and existing under the laws of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803. AstraZeneca Pharmaceuticals LP markets and sells BRILINTA®

in this judicial district and throughout the United States, and Defendant specifically directed its Notice Letters to AstraZeneca Pharmaceuticals LP.

7. On information and belief, Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Rd, Morgantown, West Virginia, 26505.

8. On information and belief, Mylan Pharmaceuticals Inc. is a pharmaceutical company that formulates, manufactures, packages, and markets generic drug products for distribution in this judicial district and throughout the United States.

9. On information and belief, Mylan Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a principal place of business at 1500 Corporate Drive, Suite 400, Canonsburg, PA 15317.

10. On information and belief, Mylan Inc. is a pharmaceutical company that develops, licenses, manufacturers, markets, and distributes generic pharmaceuticals in the United States. On information and belief, Mylan Inc. conducts its North American operations, in part, through Mylan Pharmaceuticals Inc., and together, they collaborate in formulating, manufacturing, packaging and/or marketing generic drug products for distribution in the State of West Virginia and throughout the United States.

11. On information and belief, Mylan Inc. is one of the largest generic pharmaceutical companies in the world in terms of revenue and holds top rankings in the U.S. generics prescription market in terms of sales and prescriptions dispensed.

12. On information and belief, Mylan Inc. directly and through its affiliates, including its twenty subsidiaries that have incorporated in the state of West Virginia, markets and sells drug products in the State of West Virginia and throughout the United States.

13. On information and belief, Mylan Pharmaceuticals, Inc. is a wholly-owned subsidiary of Mylan Inc., and is controlled by Mylan Inc. On information and belief, Mylan Pharmaceuticals Inc. acts as an agent for Mylan Inc. in connection with the sale of pharmaceutical products in the United States, including the State of West Virginia.

14. On information and belief, Mylan Pharmaceuticals Inc. and Mylan Inc. are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products throughout the United States, including into West Virginia.

15. On information and belief, Mylan Pharmaceuticals Inc. and Mylan Inc. acted in concert to develop the proposed generic product that is the subject of ticagrelor ANDA to seek regulatory approval from FDA to market and sell the proposed ANDA product throughout the United States, including within West Virginia.

16. On information and belief, the preparation and submission of ticagrelor ANDA by Mylan Pharmaceuticals Inc. was done at the direction, under the control, in concert with, and/or for the direct benefit of Mylan Inc.

17. On information and belief, and consistent with their practice with respect to other generic products, following FDA approval of ticagrelor ANDA, Defendant will act in concert to distribute and sell the generic product described in ticagrelor ANDA throughout the United States and within West Virginia.

JURISDICTION AND VENUE

18. Each of the preceding paragraphs 1 to 17 is re-alleged and re-incorporated as if fully set forth herein.

19. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

20. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

21. Mylan is subject to personal jurisdiction in this district.

22. This Court has personal jurisdiction over Mylan Pharmaceuticals Inc. because, *inter alia*, Mylan Pharmaceuticals Inc. is incorporated in the State of West Virginia, and Mylan Pharmaceuticals Inc.'s principal place of business is located within this judicial district, specifically in Morgantown, West Virginia.

23. This Court has personal jurisdiction over Mylan Inc. because, *inter alia*, Mylan Inc. consented to jurisdiction in West Virginia by affirmatively registering to do business as a foreign corporation in West Virginia under Control Number 70518 and by affirmatively appointing a West Virginia agent to accept service of process in West Virginia, the Corporation Service Company, 209 West Washington Street, Charleston, WV 23502.

24. Further, on information and belief, Defendant will manufacture, market, and/or sell within the United States the generic product described in the ticagrelor ANDA if FDA approval is granted. If the ticagrelor ANDA is approved, on information and belief the generic product would, among other things, be marketed and distributed in this judicial district, prescribed by physicians practicing in this judicial district, and dispensed by pharmacies located within this judicial district, and/or used by patients in this judicial district, all of which would have a substantial effect on this judicial district.

25. Furthermore, Mylan has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has availed itself of West Virginia

courts through the assertion of counterclaims. *See, e.g., Salix Pharmaceuticals, Inc. et al. v. Mylan Pharmaceuticals, Inc. et al.,* C.A. No. 15-cv-00109; *Pfizer Inc. et al v. Mylan Inc. et al.,* C.A. No. 15-cv-00004; *Teva Pharmaceuticals USA, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.,* .A. No. 14-cv-00167; *Gilead Sciences Inc. et al. v. Mylan Inc. et al.,* C.A. No. 14-cv-00099.

26. This Court also has personal jurisdiction over Mylan because, *inter alia*, Mylan has purposefully availed itself of the rights and benefits of West Virginia law by engaging in systematic and continuous contacts with the state of West Virginia. On information and belief, Mylan regularly and continuously transacts business within the state of West Virginia, including by selling pharmaceutical products in West Virginia, directly and/or through affiliates, and/or by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including West Virginia. On information and belief, Mylan Pharmaceuticals Inc. and Mylan Inc. have done so with each other's authorization, participation, assistance, and/or acting in concert with each other. On information and belief, Mylan derives substantial revenue from the sale of those products in West Virginia and has availed itself of the privilege of conducting business within the State of West Virginia.

27. On information and belief, Mylan Pharmaceuticals Inc. and Mylan Inc. operate as an integrated, unitary generic pharmaceutical business. On information and belief, when FDA inspects and issues warning letters regarding Mylan Pharmaceuticals Inc. manufacturing facilities, FDA sends the warning letters to Mylan Inc. On information and belief, Mylan Inc. issues press releases for Mylan Pharmaceuticals Inc. when generic drugs are approved by FDA, when other events concerning the commercialization of a generic drug occur, and when they are involved in litigation in connection with filing ANDAs.

28. For these reasons and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Mylan.

PATENTS-IN-SUIT

29. On June 26, 2001, the U.S. Patent and Trademark Office duly and legally issued the '910 patent, entitled "1,2,3-triazolo[4,5-d]pyrimidines as P_{2T} receptor antagonists." A true and correct copy of the '910 patent is attached hereto as **Exhibit A**. The claims of the '910 patent are valid and enforceable. AstraZeneca UK Limited is the owner of the '910 patent by assignment and has the right to enforce it.

30. On February 25, 2003, the U.S. Patent and Trademark Office duly and legally issued the '060 patent, entitled "Triazolo(4,5-d)pyrimidine compounds." A true and correct copy of the '060 patent is attached hereto as **Exhibit B**. The claims of the '060 patent are valid and enforceable. AstraZeneca UK Limited is the owner of the '060 patent by assignment and has the right to enforce it.

31. On July 31, 2007, the U.S. Patent and Trademark Office duly and legally issued the '419 patent, entitled "Trisubstituted triazolopyrimidines for use in platelet aggregation inhibition." A true and correct copy of the '419 patent is attached hereto as **Exhibit C**. The claims of the '419 patent are valid and enforceable. AstraZeneca UK Limited is the owner of the '419 patent by assignment and has the right to enforce it.

32. On September 4, 2007, the U.S. Patent and Trademark Office duly and legally issued the '124 patent, entitled "Cristalline and amorphous form of a triazolo (4,5-D) pyridimine compound." A true and correct copy of the '124 patent is attached hereto as **Exhibit D**. The claims of the '124 patent are valid and enforceable. AstraZeneca AB is the owner of the '124 patent by assignment and has the right to enforce it.

33. On April 23, 2013, the U.S. Patent and Trademark Office duly and legally issued the '934 patent, entitled "Pharmaceutical compositions." A true and correct copy of the '934 patent is attached hereto as **Exhibit E**. The claims of the '934 patent are valid and enforceable. AstraZeneca AB is the owner of the '934 patent by assignment and has the right to enforce it.

34. AstraZeneca LP is the holder of NDA No. 022433 by which FDA granted approval for the marketing and sale of ticagrelor tablets in 90 mg and 60 mg dosage strengths, to reduce the rate of cardiovascular death, myocardial infarction, and stroke in patients with acute coronary syndrome (ACS) or a history of myocardial infarction (MI). AstraZeneca markets ticagrelor tablets in the United States, through its Delaware subsidiary AstraZeneca Pharmaceuticals LP, under the trade name "BRILINTA®." FDA's official publication of approved drugs, the Orange Book, includes BRILINTA® in 90 mg and 60 mg dosage strengths together with the Orange Book Patents (the '910, '060, '419, '124, and '934 patents).

INFRINGEMENT BY DEFENDANT

35. Each of the preceding paragraphs 1 to 34 is re-alleged and re-incorporated as if fully set forth herein.

36. In letters dated September 16, 2015 and September 17, 2015 ("the Notice Letters"), Mylan notified AstraZeneca AB, AstraZeneca LP c/o AstraZeneca Pharmaceuticals LP, and AstraZeneca UK Limited, that Mylan had submitted its ticagrelor ANDA to FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)).

37. The Notice Letters state that Mylan is seeking approval from FDA to engage in the commercial manufacture, use, and sale of generic ticagrelor tablets before the expiration of the Orange Book Patents. On information and belief, Mylan intends to engage in the commercial manufacture, use, and sale of its generic ticagrelor tablets after receiving FDA approval to do so.

38. In the Notice Letters, Mylan notified AstraZeneca that its ANDA contained a "Paragraph IV certification" asserting that each of Orange Book Patents is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Mylan's generic ticagrelor tablets.

39. This Complaint is being filed before the expiration of the forty-five days from the date AstraZeneca received the first of the Notice Letters.

COUNT I (INFRINGEMENT OF THE '910 PATENT)

40. Each of the preceding paragraphs 1 to 39 is re-alleged and re-incorporated as if fully set forth herein.

41. Defendant's submission of its ticagrelor ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic ticagrelor tablets prior to the expiration of the '910 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

42. On information and belief, upon FDA approval of Defendant's ticagrelor ANDA, Defendant will further infringe at least one claim of the '910 patent by making, using, offering to sell, and selling its generic ticagrelor tablets in the United States and/or importing such tablets into the United States in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c) unless enjoined by the Court.

43. If Defendant's marketing and sale of generic ticagrelor tablets prior to expiration of the '910 patent and all other relevant exclusivities is not enjoined, AstraZeneca will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II (INFRINGEMENT OF THE '060 PATENT)

44. Each of the preceding paragraphs 1 to 43 is re-alleged and re-incorporated as if fully set forth herein.

45. Defendant's submission of its ticagrelor ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic ticagrelor tablets prior to the expiration of the '060 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

46. On information and belief, upon FDA approval of Defendant's ticagrelor ANDA, Defendant will further infringe at least one claim of the '060 patent by making, using, offering to sell, and selling its generic ticagrelor tablets in the United States and/or importing such tablets into the United States in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c) unless enjoined by the Court.

47. If Defendant's marketing and sale of generic ticagrelor tablets prior to expiration of the '060 patent and all other relevant exclusivities is not enjoined, AstraZeneca will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT III (INFRINGEMENT OF THE '419 PATENT)

48. Each of the preceding paragraphs 1 to 47 is re-alleged and re-incorporated as if fully set forth herein.

49. Defendant's submission of its ticagrelor ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic ticagrelor tablets prior to the expiration of the '419 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

50. On information and belief, upon FDA approval of Defendant's ticagrelor ANDA, Defendant will further infringe at least one claim of the '419 patent by making, using, offering to sell, and selling its generic ticagrelor tablets in the United States and/or importing such tablets into the United States in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c) unless enjoined by the Court.

51. If Defendant's marketing and sale of generic ticagrelor tablets prior to expiration of the '419 patent and all other relevant exclusivities is not enjoined, AstraZeneca will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT IV (INFRINGEMENT OF THE '124 PATENT)

52. Each of the preceding paragraphs 1 to 51 is re-alleged and re-incorporated as if fully set forth herein.

53. Defendant's submission of its ticagrelor ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic ticagrelor tablets prior to the expiration of the '124 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

54. On information and belief, upon FDA approval of Defendant's ticagrelor ANDA, Defendant will further infringe at least one claim of the '124 patent by making, using, offering to sell, and selling its generic ticagrelor tablets in the United States and/or importing such tablets into the United States in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c) unless enjoined by the Court.

55. If Defendant's marketing and sale of generic ticagrelor tablets prior to expiration of the '124 patent and all other relevant exclusivities is not enjoined, AstraZeneca will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT V (INFRINGEMENT OF THE '934 PATENT)

56. Each of the preceding paragraphs 1 to 55 is re-alleged and re-incorporated as if fully set forth herein.

57. Defendant's submission of its ticagrelor ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic ticagrelor tablets prior to the expiration of the '934 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

58. If Defendant's marketing and sale of generic ticagrelor tablets prior to expiration of the '934 patent and all other relevant exclusivities is not enjoined, AstraZeneca will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, AstraZeneca respectfully prays that this Court grant the following relief:

59. A judgment that the claims of the Orange Book Patents are not invalid, not unenforceable, and are infringed by Defendant's submission of its ticagrelor ANDA, and that Defendant's making, using, offering to sell, or selling in the United States, or importing into the United States Defendant's generic ticagrelor tablets will infringe the Orange Book Patents.

60. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Defendant's ticagrelor ANDA shall be a date which is not earlier than the latest expiration date of the Orange Book Patents, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

61. An order permanently enjoining Defendant, its affiliates, subsidiaries, and each of its officers, agents, servants and employees, and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States Defendant's generic ticagrelor tablets until after the latest expiration date of the Orange Book Patents, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

62. Damages or other monetary relief to AstraZeneca if Defendant engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Defendant's generic ticagrelor tablets prior to the latest expiration date of the Orange Book

Patents, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

63. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

DATED: November 2, 2015

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